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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,441	04/15/2004	Patrick M. Hughes	17686 (OCU)	1056

7590 10/31/2007

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EXAMINER	
MAASHO, KERIMA K	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
10/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,441	HUGHES ET AL.	
	Examiner	Art Unit	
	Kerima Maasho	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,23-27 and 29-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-21,23-27 and 29-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

The amendment filed on 08/06/2007 has been entered into the record. Claims 22 and 28 are cancelled. Claims 1-21, 23-27 and 29-33 are pending in the application.

Rejections Withdrawn

The rejection of claims 16, 18, 21-23, 26, 28 and 30 under 35 U.S.C. 112, second paragraph, as being indefinite for the use of the term "substantially identical", is withdrawn based on Applicants amendment of the claims.

Response to Arguments

Rejections Maintained

Claim Rejections - 35 USC § 102(b):

The rejection of claims 1-25 under 35 U.S.C. 102(b) as being anticipated by Donovan U.S. patent 6,506,399 B2 (made of record on the IDS filed 6/30/04); and the rejection of claims 16-23 and 25-33 under 35 U.S.C. 102(b) as being anticipated by Donovan U.S. patent 6,312,708 are maintained.

Applicants' arguments have been carefully considered but are not persuasive. Applicants argue that US Patent No. 6,506,399 does not disclose all of the limitations of the claims 1) a neurotoxin component associated and 2) an acidity regulating component for establishing in vivo a pH in the vicinity of the neurotoxin component of

less than about 7. Applicants argue that '399 patent does not expressly disclose the second element, an acidity regulating component. The specification of the instant application discloses that the acidity-regulating component may include at least one of biodegradable monomers and oligomers (p 15). Monomers such as lactide and glycolide are taught in US Patent No. 6,506,399 as in the present invention, it appears that the monomers of the reference and the instant invention are the same hence the basis for the inherency. "The discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977). In the instant case, the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product. . . . Whether the rejection is based on `inherency' under 35 U.S.C. § 102, on `prima facie obviousness' under 35 U.S.C. § 103, jointly or alternatively, the burden of proof is the same, and its fairness is evidenced by the PTO's inability to manufacture products or to obtain and compare prior art products.

Claim Rejections - 35 USC § 103:

The rejection of claims 1, 26-30 under 35 U.S.C. 103 as being obvious over Donovan U.S. patent No. 6,506,399 in view of Agarwal U.S. patent No. 5,741,329 is maintained. Claims 1 and 26-30 refer to the acidity-regulating component whereby a method of controlling the pH in the vicinity of biodegradable implants was described. Applicants' arguments have been carefully considered but are not persuasive. Applicants argue that the Agarwal reference seeks to maintain a constant pH, and not create shift the pH to an acidic one as the claimed invention. The rejection is maintained because Agarwal et al address the problems associated with shifts in pH due to biodegradable polymer breakdown products and also their reference to acidic pH being a problem, their teaching in fact discloses a pH-controlling device which depending on the requirement of the implant the pH controlling substance of the device may comprise an alkaline, acidic or buffering component.

U.S. patent No. 6,506,399 teaches specifically about a biodegradable botulinum toxin implant and the importance of maintaining acidic environment for the controlled release of botulinum toxin in vivo. Pure botulinum toxin is labile and that botulinum toxin type A complex are extremely susceptible to denaturation due to heat and alkaline conditions. U.S. patent No. 6,506,399 teaches that denaturation of the encapsulated neurotoxin, botulinum toxin type A, in the body at 37 degrees C. for a prolonged period of time can be reduced among other things with lyophilization from an acidic solution using a specific polymer matrix composition. Therefore the alkaline lability of the neurotoxin is an obvious motivation for the development of an acidity pH-regulating component.

Agarwal et al discloses a method of controlling the pH in the vicinity of biodegradable implants and teach a pH-controlling device that comprise a biodegradable polymer and a pH-controlling substance, particularly an alkaline, acidic or buffering agent (see abstract). The pH controlled implantable device taught by Agarwal et al comprises the biodegradable polymer polylactic acid, polyglycolic acid, polycaprolactone, copolymers thereof, or mixtures thereof (column 4, lines 48-51). The pH controlling substance of the device may comprise an alkaline substance, an acidic substance or a buffering agent, depending upon the acidic or alkaline nature of the polymeric breakdown products of the particular biodegradable polymer employed (column 5, lines 4-8). Therefore, depending on the requirement of the implant the pH controlling substance of the device may comprise an acidic component as in the instant invention. The combined teachings of Donovan (a motivation and reveal the inherent properties of the monomers from which the biodegradable polymer is derived) and Agarwal et al (the pH-controlling device that is regulated to give a desired pH) render the claimed invention obvious.

The rejection of claims 1, 11-13 are rejected under 35 U.S.C. 103 as being obvious over Donovan U.S. patent No. 6,506,399 in view of Gurny et al U.S. patent No. 6,440,460. Claims 1, and 11-13 refer to the acidity-regulating component to be effective in maintaining a pH of the implant to a value of less than 7, within a range of about 3 to 7. Applicants' arguments have been carefully considered but are not persuasive. Applicants argue that the Gurney et al reference teaches a decreasing pH being a

problem and that they do not seek to maintain an acidic pH, but to buffer the pH to maintain it a physiologically acceptable levels.

The rejection is maintained because the instant claims are directed to a range of pH (3 to 7) wherein part of the physiological acceptable pH range (5.5 to 7.5) of Gurney et al's teaching fall in.

U.S. patent No. 6,506,399 teaches specifically about a biodegradable botulinum toxin implant and the importance of maintaining acidic environment for the controlled release of botulinum toxin in vivo. Gurny et al. teaches generally about pharmaceutical compositions containing buffered polymers of biodegradable implant. Together the teachings of Donovan and Gurny give a basis for claims 1, 11-13, by offering a motivation as well as revealing the inherent properties of the monomers from which the biodegradable polymer is derived. Basic salts of the polymer can be used to regulate or neutralize the polymer microclimate pH to levels necessary to retain the structure and biological activity of encapsulated labile proteins.

Conclusion

All claims stand rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kerima Maasho whose telephone number is 571-270-3055. The examiner can normally be reached on Monday-Thursday, 7:30am-5:00pm, ALT. Friday, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kerima Maasho/
Patent Examiner, Art Unit 1645

/Bruce Campell/
Supervisory Patent Examiner
Art Units 1645 (acting) and 1648